

THOMAS L. GARTHWAITE, M.D. Director and Chief Medical Officer

FRED LEAF

Chief Operating Officer

COUNTY OF LOS ANGELES DEPARTMENT OF HEALTH SERVICES 313 N. Figueroa, Los Angeles, CA 90012 (213) 240-8101

January 8, 2004

The Honorable Board of Supervisors County of Los Angeles 383 Kenneth Hahn Hall of Administration 500 West Temple Street Los Angeles, California 90012

Dear Supervisors:

### AGREEMENT AMENDMENTS FOR THE HIV/AIDS ADULT SPECTRUM OF DISEASE COHORT STUDY

(All Districts) (3 Votes)

### IT IS RECOMMENDED THAT YOUR BOARD:

Approve and instruct the Director of Health Services, or his designee, (Director) to sign three agreement amendments, substantially similar to Exhibits I through III, to reduce the term of the agreements from December 31, 2005 to June 30, 2004 and to decrease the County maximum obligation retroactive to January 1, 2004 through June 30, 2004, with Harbor-UCLA Research and Education Institute, No. H-213237-2, by \$45,254, from \$90,507 to \$45,253; Health Research Association, No. H-213193-2, by \$160,421, from \$320,841 to \$160,420; and Kaiser Foundation Research Institute, No. H-207839-2 by \$58,688, from \$127,816 to \$69,128, for a total maximum obligation reduction from \$539,164 to \$274,801, for the HIV/AIDS Adult Spectrum of HIV-Related Diseases Cohort Study (ASD), 100% offset by forthcoming grant funding from the Federal Centers for Disease Control and Prevention (CDC), pending receipt of the Calendar Year (CY) 2003 CDC grant award Amendment No. 4 and CY 2004 CDC grant award.

### PURPOSE/JUSTIFICATION OF THE RECOMMENDED ACTION:

In approving the recommended action, the Board is authorizing the Director to sign agreement amendments to reduce the term of the agreements from December 31, 2005 to June 30, 2004, for HIV/AIDS ASD project services with Harbor-UCLA Research and Education Institute (REI), Agreement No. H-213237-2; Health Research Association (HRA), Agreement No. H-213193-2, and Kaiser Foundation Research Institute (Kaiser), Agreement No. H-207839-2, retroactive to January 1, 2004, through June 30, 2004, pending receipt of the Calendar Year 2003 CDC grant award Amendment No. 4 and the CY 2004 CDC grant award.

Gloria Molina

First District

Yvonne Brathwaite Burke Second District

> Zev Yaroslavsky Third District

Don Knabe Fourth District

Michael D. Antonovich Fifth District The Honorable Board of Supervisors January 8, 2004 Page 2

The CDC ASD project protocol requires mandated continuity for established HIV/AIDS epidemiology cohort groups of HIV/AIDS patient records and oversight. The amendments with REI, HRA, and Kaiser will keep this study intact and will maintain the continuity of services and will allow the continued expenditure of grant funding from the CDC for this longitudinal medical records-based cohort study from January 1, 2004 through June 30, 2004, consistent with the Board's policy for grant-funded activities.

Current County policy and guidelines require the timely submission of contracts for Board approval. However, these amendments were not scheduled for placement on the Board's agenda three weeks prior to their effective dates due to late notification from the grantor of the change in term and reduced funding for the ASD study, from January 1, 2004 through December 31, 2005, to January 1, 2004, through June 30, 2004.

### FISCAL IMPACT/FINANCING:

The total revised contractual obligation for the three HIV/AIDS ASD Cohort Study agreements will be reduced from \$539,164, to \$274,801, 100% offset by forthcoming CDC HIV/AIDS surveillance and seroprevalence funds. Funding was reduced from \$90,507 to \$45,253 for REI, from \$320,841 to \$160,420 for HRA and from \$127,816 to \$69,128 for Kaiser.

Funding for this program is included in the Fiscal Year 2003-04 Adopted Budget. There is no net County cost.

### FACTS AND PROVISIONS/LEGAL REQUIREMENTS:

Since February 1983, the County has accepted financial assistance from the CDC to support HIV/AIDS surveillance and seroprevalence activities.

The ASD is a medical records-based cohort study initiated by the CDC in 1990 to help better define the spectrum of HIV-related diseases. The County has been a collaborating ASD site since the inception of the ASD study. The study began with patients from LAC+USC Medical Center, REI, and Kaiser. These sites were selected for participation because they are located in different parts of the County, serve large and racially diverse populations, and report approximately 1/3 of all HIV/AIDS cases locally.

Since 1990, REI, HRA, and Kaiser have been collecting data for the ASD study through subcontract agreements and agreements with the County.

On December 17, 2002, the Board adopted agreement amendments with REI, HRA, and Kaiser to conduct the ASD Cohort Study through December 31, 2003 with two 12-month automatic renewal periods through December 31, 2005.

On December 9, 2003, among other actions, the Board accepted the CY 2003 CDC grant Amendments 2 and 3 for the ASD study and delegated authority to the Director to accept CY 2004 grant funds.

On September 16, 2003, the CDC informed the Department's HIV Epidemiology Program that the ASD study would terminate June 30, 2004, and as a result funding for each agreement would be reduced effective in CY 2004. This action was not placed on the December 9, 2003 Board agenda because the Department had not yet received necessary CDC documentation of the termination of the ASD study.

The Honorable Board of Supervisors January 8, 2004 Page 3

Since this represents a decrease in funding and a change in term, the Department of Health Services is requesting the Board's approval to reduce the term of the three ASD contract agreements at a total allocation of \$274,801 for the period January 1, 2004 through June 30, 2004.

County Counsel has reviewed the amendments (Exhibits I - III) as to form.

Attachment A provides additional information.

### IMPACT ON CURRENT SERVICES (OR PROJECTS):

Approval of the amendments will provide the necessary continuity of the ASD study which will collect pertinent data on HIV-related diseases.

When approved, this Department requires three signed copies of the Board's action.

Respectfully submitted.

Thomas L. Garthwaite, M.D.

Director and Chief Medical Officer

TLG:pm

Attachments (1)

c: Chief Administrative Officer

County Counsel

Executive Officer, Board of Supervisors

BLETCD3106.ES.wpd

Health Research Association

1640 Marengo Street, 3rd Floor

Los Angeles, California 90033

Telephone: (323) 223-4091

Email: pratt@scientist.com

Elizabeth C. Pratt

Acting President and CEO

### **SUMMARY OF AMENDMENTS**

B.

Attention:

### TYPE OF SERVICES:

HIV/AIDS epidemiology services.

#### 1. **AGENCY NAMES AND CONTACT PERSONS:**

A. Harbor-UCLA Research and Education Institute

1124 West Carson Street Torrance, California 90502 Attention: Ashley Hogan

V.P. and Research Admin. & Services

Telephone: (310) 222-3621 Email: <u>cwsteers@rei.edu</u>

C. Kaiser Foundation Research Institute

1800 Harrison Street, 16th Floor Oakland, California 94612-3433 Attention: Nancy King, Director Telephone: (510) 987-4790

Email: Nancy.King@KP.Org

Southern California Permanente Medical Group Attention: Velma Alarcon, Grants Administrator

Telephone: (626) 564-3416 Email: Velam.Alarcon@kp.org

### 2. **AMENDMENT TERMS:**

The terms of the agreements will be changed from January 1, 2004 through December 31, 2005, to January 1. 2004 through June 30, 2004.

#### 3. FINANCIAL INFORMATION - January 1, 2004 through June 30, 2004:

Maximum County Obligation \$274,801 CDC HIV/AIDS Surveillance and Seroprevalence funds: 274,801 \$ -0-

Net County Cost

#### 4. GEOGRAPHIC AREA SERVED:

Countywide.

### 5. ACCOUNTABLE FOR MONITORING AND EVALUATION:

Paul Simon, M.D., MPH, Director, Health Assessment and Epidemiology.

#### 6. APPROVALS:

Public Health: John F. Schunhoff, Ph.D., Chief of Operations

Contracts and Grants Division: Diana Sayler, Interim Chief

County Counsel (as to form): Kelly Auerbach Hassel, Deputy County Counsel

## HUMAN IMMUNODEFICIENCY VIRUS (HIV) ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS) ADULT SPECTRUM OF HIV-RELATED DISEASES COHORT STUDY SERVICES AGREEMENT

Amendment No. 2

	THIS AMENDMENT is	s made and	entered into this	day
of _		, 2004,		
	by and between		COUNTY OF LOS ANGELES "County"),	(hereafter
	and		HARBOR-UCLA RESEARCH A EDUCATION INSTITUTE (hereafter "Contractor	

WHEREAS, reference is made to that certain document entitled "HUMAN IMMUNODEFICIENCY VIRUS (HIV) ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS) ADULT SPECTRUM OF HIV-RELATED DISEASES COHORT STUDY SERVICES AGREEMENT", dated December 18, 2001, further identified as Agreement No. H-213237 and any amendments thereto (hereafter "Agreement"); and

WHEREAS, it is the intent of the parties hereto to reduce the term of Agreement and to provide for other changes set forth herein; and

WHEREAS, said Agreement provides that changes may be made in the form of a written Amendment which is formally approved and executed by the parties.

NOW, THEREFORE, the parties agree as follows:

- 1. This Amendment shall be effective January 1, 2004 through June 30, 2004.
- 2. The first two subparagraphs of Paragraph 1, <u>TERM</u>, shall be amended to read as follows:
  - "1. TERM: The term of this Agreement shall commence on December 18, 2001 and continue in full force and effect through December 31, 2003. Said Agreement shall thereafter be automatically renewed for one (1) six-month period, effective January 1, 2004 through June 30, 2004, subject to the availability of federal, State, or County funding sources. This Agreement may be terminated, with or without cause, by contractor upon giving at least thirty (30) days advance written notice thereof to County. In any event County may terminate this Agreement in accordance with the ADDITIONAL PROVISIONS hereunder.

County may also suspend the performance of services hereunder, in whole or in part, within thirty (30) days notice to Contractor. County's notice shall set forth the reasons for the suspension, the extent of the suspension, and the requirements for full restoration of the performance obligations."

- 3. Paragraph 2, <u>DESCRIPTION OF SERVICES</u>, shall be amended to read as follows:
  - "2. <u>DESCRIPTION OF SERVICES</u>: Contractor shall provide the services described in Exhibits A and D-1, attached hereto and incorporated herein by reference."
- 4. Exhibit D shall be deleted in its entirety and shall be replaced by Exhibit D-1.
- 5. Paragraph 3, <u>MAXIMUM OBLIGATION OF COUNTY</u>, shall be amended to read as follows:

### "3. MAXIMUM OBLIGATION OF COUNTY:

- A. During the period January 1, 2002 through
  December 31, 2002, the maximum obligation of County for
  all services provided hereunder shall not exceed Ninety
  Thousand, Five Hundred Seven Dollars (\$90,507). Such
  maximum obligation is comprised entirely of Federal
  Centers for Disease Control and Prevention, HIV/AIDS
  Surveillance and Seroprevalence Program funds. This sum
  represents the total maximum obligation of County as
  shown in Schedule 1, attached hereto and incorporated
  herein by reference.
- B. During the period January 1, 2003 through December 31, 2003, the maximum obligation of County for all services provided hereunder shall not exceed Ninety

Thousand, Five Hundred Seven Dollars (\$90,507). Such maximum obligation is comprised entirely of Federal Centers for Disease Control and Prevention, HIV/AIDS Surveillance and Seroprevalence Program funds. This sum represents the total maximum obligation of County as shown in Schedule 2, attached hereto and incorporated herein by reference.

- C. During the period January 1, 2004 through June 30, 2004, the maximum obligation of County for all services provided hereunder shall not exceed Forty-Five Thousand, Two Hundred Fifty-Three Dollars (\$45,253).

  Such maximum obligation is comprised entirely of Federal Centers for Disease Control and Prevention, HIV/AIDS

  Surveillance and Seroprevalence Program funds. This sum represents the total maximum obligation of County as shown in Schedule 3-A, attached hereto and incorporated herein by reference."
- 6. Schedule 3 shall be deleted in its entirety and shall be replaced by Schedule 3-A.
- 7. Schedule 4 shall be deleted in its entirety from Agreement.
- 8. Paragraph 6, <u>COMPENSATION</u>, shall be amended to read as follows:
  - "6. <u>COMPENSATION</u>: County agrees to compensate

    Contractor for performing services hereunder for actual

reimbursable net cost as set forth in Schedules 1, 2, and 3-A and the PAYMENT Paragraph of the ADDITIONAL PROVISIONS, all attached hereto."

- 9. Paragraph 9, <u>CONFLICT OF TERMS</u>, shall be amended to read as follows:
  - "9. <u>CONFLICT OF TERMS</u>: To the extent there exists any conflict between the language of this Agreement and that of any of the exhibits and schedules attached hereto, the language in this Agreement shall govern and prevail, and the remaining exhibits and schedules shall govern and prevail in the following order:

Exhibits A and D-1
Schedules 1, 2, and 3-A
Exhibit C"

- 10. Exhibit D-1, SCOPE OF WORK FOR HIV/AIDS ADULT SPECTRUM OF HIV-RELATED DISEASES COHORT STUDY SERVICES, attached to this Amendment and incorporated in Agreement by reference.
- 11. Schedule 3-A, BUDGET FOR HIV/AIDS ADULT SPECTRUM OF HIV-RELATED DISEASES COHORT STUDY SERVICES, is attached to this Amendment and incorporated in Agreement by reference.
- 12. Except for the changes set forth hereinabove, Agreement shall not be changed in any respect by this Amendment.

IN WITNESS WHEREOF, the Board of Supervisors of the County of Los Angeles has caused this Amendment to be subscribed by its

Director of Health Services, and Contractor has caused this

Amendment to be subscribed in its behalf by its duly authorized

officer, the day, month, and year first above written.

COUNTY OF LOS ANGELES

By	
	Thomas L. Garthwaite, M.D. Director and Chief Medical Officer
	BOR-UCLA RESEARCH AND EDUCATION TITUTE
	Contractor
Ву	
_	Signature
	Printed Name
Tit	le
	(AFFIX CORPORATE SEAL)

APPROVED AS TO FORM
BY THE OFFICE OF THE COUNTY COUNSEL
LLOYD W. PELLMAN
County Counsel

APPROVED AS TO CONTRACT ADMINISTRATION:

Ву		
_	Contracts	Administration

cd3107es.wpd

### EXHIBIT D-1

### HARBOR-UCLA RESEARCH AND EDUCATION INSTITUTE

### HUMAN IMMUNODEFICIENCY VIRUS (HIV) ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS) ADULT SPECTRUM OF HIV-RELATED DISEASES COHORT STUDY

- 1. <u>DEFINITION</u>: HIV/AIDS Adult Spectrum of HIV-Related Diseases Cohort Study is a medical records-based study to help better define the spectrum of HIV-related disease. Medical records are reviewed to collect basic demographic data, information on HIV-exposure category, AIDS-defining conditions, other infections and conditions, treatment and prophylaxis, and laboratory data.
- 2. <u>PERSONS TO BE SERVED</u>: HIV/AIDS Adult Spectrum of HIV-Related Diseases Cohort Study shall be conducted at Harbor-UCLA Medical Center for all patients, thirteen (13) years and over, who have HIV disease or an AIDS diagnosis.
- 3. <u>SERVICE DELIVERY SITE</u>: Contractor's facility where services are to be provided hereunder is located at: 1124 West Carson Street, Torrance, California 90502.

Contractor shall request approval from HIV EPIDEMIOLOGY PROGRAM (HEP) in writing a minimum of thirty (30) days before terminating services at such location and before commencing services at any other locations.

4. <u>COUNTY'S MAXIMUM OBLIGATION</u>: During the period of January 1, 2004 through June 30, 2004, that portion of County's maximum obligation which is allocated under this Exhibit for the

HIV/AIDS Adult Spectrum of HIV-Related Diseases Cohort Study shall not exceed Forty-Five Thousand, Two Hundred Fifty-Three Dollars (\$45,253).

- 5. <u>COMPENSATION</u>: County agrees to compensate Contractor for performing services hereunder for actual reimbursable net cost as set forth in Schedule 3-A. Payment for services provided hereunder shall be subject to the provisions set forth in the PAYMENT Paragraph of the ADDITIONAL PROVISIONS of this Agreement.
- 6. <u>SERVICES TO BE PROVIDED</u>: Contractor shall conduct the HIV/AIDS Adult Spectrum of HIV-Related Diseases Cohort Study in accordance with procedures formulated and adopted by Contractor's staff, consistent with law, regulations, and the terms of this Agreement. Services to be provided shall include, but shall not be limited to:
  - A. Identifying and enrolling all patients with HIV disease or an AIDS diagnosis age thirteen (13) years and older.
  - B. Reviewing the medical records to abstract diagnostic treatment and laboratory information for each admission.
    - C. Maintaining data on all study participants.
    - D. Tracking enrolled participants throughout the study.
- 7. <u>REPORTS</u>: Subject to the reporting requirements of the REPORTS Paragraph of the ADDITIONAL PROVISIONS of this Agreement attached hereto, Contractor shall submit the following reports:

- A. <u>Monthly Report</u>: Contractor shall submit to HEP monthly report no later than thirty (30) days after the end of each calendar month. Monthly reports shall clearly reflect all required information as specified, in a narrative report format, identifying the progress of the study as provided by HEP.
- B. Annual Report: Contractor shall submit to HEP an annual report within the time period as directed for each year. Annual reports shall include all the required information and be completed in the correct format.
- 8. ANNUAL TUBERCULOSIS SCREENING FOR STAFF: Prior to employment or provision of services hereunder, and annually thereafter, Contractor shall obtain and maintain documentation of tuberculosis screening for each employee, volunteer, and consultant providing services hereunder. Such tuberculosis screening shall consist of tuberculin skin test (Mantoux test) and/or written certification by a physician that the person is free from active tuberculosis based on a chest x-ray.

Contractor shall adhere to Exhibit C, "Guidelines for Staff Tuberculosis Screening", attached hereto and incorporated herein by reference. Director shall notify Contractor of any revision of these Guidelines, which shall become part of this Agreement.

9. PROGRAM RECORDS: Contractor shall, at a minimum, maintain program/participant records as follows:

- A. Each participant's record shall include, but shall not be limited to, documentation of HIV disease, and/or AIDS diagnosis.
- B. Documentation of supervisorial review of each participant's record.
- 10. <u>QUALITY IMPROVEMENT</u>: Contractor shall develop and submit to HEP within ninety (90) days of the execution of this Agreement, its written Quality Improvement (QI) program. The program shall include requirements for an internal QI committee, a mechanism for obtaining client input, and identify the QI program's structure, process, and desired outcome.

## LOS ANGELES COUNTY DEPARTMENT OF HEALTH SERVICES HIV EPIDEMIOLOGY PROGRAM ADULT SPECTRUM OF HIV-RELATED DISEASES COHORT STUDY SUBCONTRACT: HARBOR/UCLA (REI)

### January 1, 2004 - June 30, 2004

		MONTHLY SALARY	% OF TIME		TOTAL
l.	PERSONNEL				
	Full Time Faculty				
	Co-Principal Investigator	14,841	2.5%	6	2,226
	Subtotal Full-time Faculty				2,226
	Full Time Employees		000/	•	00.054
	Medical Records Abstractor	4,344	80%	6	20,851
	Subtotal Full-time Employees				20,851
	Part Time Employees				
	Asst. Med. Rec. Abstractor	2,500	26%	6	3,900
	Subtotal Part-time Employees				3,900
	Total Employees				26,977
	Employee Benefits				
	Full-time Faculty @ 29.99% (1/1/04 - 6/30/04)				668
	Full-time Employees @ 31.50% (1/1/04 - 6/30/04)				6,568
	Part-time Employees @ 15.20% (1/1/04 - 6/30/04)				593 <b>7,829</b>
	Total Employee Benefits				7,029
	Total Salaries and Employee Benefits				34,806
II.	OPERATING EXPENSES				
	Mileage/Travel				85
	Equipment Maintenance				150
	Photocopy				88
	Office Supplies				364
	Total Operating Expenses				687
	Total Direct Cost				35,493
III.	INDIRECT COST @ 27.5%				9,760
	Based on total direct cost				
IV.	TOTAL SUB-CONTRACT				\$45,253

S:/Grants/CDCPro04/SurvSero/ASDCONTO

## HUMAN IMMUNODEFICIENCY VIRUS (HIV) ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS) ADULT SPECTRUM OF HIV-RELATED DISEASES COHORT STUDY SERVICES AGREEMENT

Amendment No. 2

	THIS AMENDMENT	is made and entered	into this day
of _		, 2004,	
	by and between	COUNTY "County	OF LOS ANGELES (hereafter"),
	and		RESEARCH ASSOCIATION ter "Contractor").

WHEREAS, reference is made to that certain document entitled "HUMAN IMMUNODEFICIENCY VIRUS (HIV) ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS) ADULT SPECTRUM OF HIV-RELATED DISEASES COHORT STUDY SERVICES AGREEMENT", dated December 18, 2001, and further identified as Agreement No. H-213193 and any amendments thereto (hereafter "Agreement"); and

WHEREAS, it is the intent of the parties hereto to reduce the term of the Agreement and to provide for other changes set forth herein; and

WHEREAS, said Agreement provides that changes may be made in the form of a written Amendment which is formally approved and executed by the parties.

NOW, THEREFORE, the parties agree as follows:

1. This Amendment shall be effective January 1, 2004.

- 2. The first two subparagraphs of Paragraph 1, <u>TERM</u>, shall be amended to read as follows:
  - "1. TERM: The term of this Agreement shall commence on January 1, 2002 and continue in full force and effect through December 31, 2003. Said Agreement shall thereafter be automatically renewed for one (1) six-month period effective January 1, 2004 through June 30, 2004, subject to the availability of federal, State, or County funding sources. This Agreement may be terminated, with or without cause, by contractor upon giving at least thirty (30) days advance written advance written notice thereof to County. In any event County may terminate this Agreement in accordance with the ADDITIONAL PROVISIONS hereunder.

County may also suspend the performance of services hereunder, in whole or in part, within thirty (30) days notice to Contractor. County's notice shall set forth the reasons for the suspension, the extent of the suspension, and the requirements for full restoration of the performance obligations."

- 3. Paragraph 2, <u>DESCRIPTION OF SERVICES</u>, shall be amended to read as follows:
  - "2. <u>DESCRIPTION OF SERVICES</u>: Contractor shall provide the services described in Exhibit A and D-1, attached hereto and incorporated herein by reference."

- 4. Exhibit D shall be deleted in its entirety and shall be replaced by Exhibit D-1.
- 5. Paragraph 3, <u>MAXIMUM OBLIGATION OF COUNTY</u>, shall be amended to read as follows:

### "3. MAXIMUM OBLIGATION OF COUNTY:

- A. During the period January 1, 2002 through

  December 31, 2002, the maximum obligation of County for

  all services provided hereunder shall not exceed Three

  Hundred Nineteen Thousand, Thirty-Three Dollars

  (\$319,033). Such maximum obligation is comprised

  entirely of Federal Centers for Disease Control and

  Prevention, HIV/AIDS Surveillance and Seroprevalence

  Program funds. This sum represents the total maximum

  obligation of County as shown in Schedule 1, attached

  hereto and incorporated herein by reference.
- B. During the period January 1, 2003 through
  December 31, 2003, the maximum obligation of County for
  all services provided hereunder shall not exceed Three
  Hundred Twenty Thousand, Eight Hundred Forty-One Dollars
  (\$320,841). Such maximum obligation is comprised
  entirely of Federal Centers for Disease Control and
  Prevention, HIV/AIDS Surveillance and Seroprevalence
  Program funds. This sum represents the total maximum
  obligation of County as shown in Schedule 2, attached

hereto and incorporated herein by reference.

- C. During the period January 1, 2004 through June 30, 2004, the maximum obligation of County for all services provided hereunder shall not exceed One Hundred Sixty Thousand, Four Hundred Twenty Dollars (\$160,420). Such maximum obligation is comprised entirely of Federal Centers for Disease Control and Prevention, HIV/AIDS Surveillance and Seroprevalence Program funds. This sum represents the total maximum obligation of County as shown in Schedule 3-A, attached hereto and incorporated herein by reference."
- 6. Schedule 3 shall be deleted in its entirety and shall be replaced by Schedule 3-A.
- 7. Schedule 4 shall be deleted in its entirety from Agreement.
- 8. Paragraph 6, <u>COMPENSATION</u>, shall be amended to read as follows:
  - "6. <u>COMPENSATION</u>: County agrees to compensate

    Contractor for performing services hereunder for actual

    reimbursable net costs as set forth in Schedules 1, 2,

    and 3-A and the PAYMENT Paragraph of this Agreement."
- 9. Paragraph 7, <u>CONFLICT OF TERMS</u>, shall be amended to read as follows:

"7. CONFLICT OF TERMS: To the extent there exists any conflict between the language of this Agreement and that of any of the exhibits and schedules attached hereto, the language in this Agreement shall govern and prevail, and the remaining exhibits and schedules shall govern and prevail in the following order:

Exhibits A and D-1 (Exhibit B does not exist)

Schedules 1, 2, and 3-A

Exhibit C"

- 10. Exhibit D-1, SCOPE OF WORK FOR HIV/AIDS ADULT SPECTRUM OF HIV-RELATED DISEASES COHORT STUDY SERVICES, is attached to this Amendment and incorporated herein by reference.
- 11. Schedule 3-A, BUDGET FOR HIV/AIDS ADULT SPECTRUM OF HIV-RELATED DISEASES COHORT STUDY SERVICES, is attached to this Amendment and incorporated in Agreement by reference.
- 12. Except for the changes set forth hereinabove, Agreement shall not be changed in any respect by this Amendment.

IN WITNESS WHEREOF, the Board of Supervisors of the County of Los Angeles has caused this Amendment to be subscribed by its

/

Director of Health Services, and Contractor has caused this

Amendment to be subscribed in its behalf by its duly authorized

officer, the day, month, and year first above written.

COUNTY OF LOS ANGELES

Ву	
-	Thomas L. Garthwaite, M.D. Director and Chief Medical Officer
HEA	ALTH RESEARCH ASSOCIATION
	Contractor
Ву	
_	Signature
	Printed Name
Tit	tle
	(AFFIX CORPORATE SEAL)

APPROVED AS TO FORM
BY THE OFFICE OF THE COUNTY COUNSEL
LLOYD W. PELLMAN
County Counsel

APPROVED AS TO CONTRACT ADMINISTRATION:

By Contracts Administration

cd3108es.wpd

### EXHIBIT D-1

### HEALTH RESEARCH ASSOCIATION

### HUMAN IMMUNODEFICIENCY VIRUS (HIV) ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS) ADULT SPECTRUM OF HIV-RELATED DISEASES COHORT STUDY

- 1. <u>DEFINITION</u>: HIV/AIDS Adult Spectrum of HIV-Related
  Diseases Cohort Study is a medical records-based study to help
  better define the spectrum of HIV-related disease. Medical
  records are reviewed to collect basic demographic data,
  information on HIV-exposure category, AIDS-defining conditions,
  other infections and conditions, treatment and prophylaxis, and
  laboratory data.
- 2. PERSONS TO BE SERVED: HIV/AIDS Adult Spectrum of HIV-Related Diseases Cohort Study shall be conducted at Los Angeles
  County + University of Southern California Medical Center for all patients, thirteen (13) years and over, who have HIV disease or an AIDS diagnosis.
- 3. <u>SERVICE DELIVERY SITE</u>: Contractor's facility where services are to be provided hereunder is located at: Los Angeles County + University of Southern California Medical Center, 1640 Marengo Street, 7th Floor, Los Angeles, CA 90033.

Contractor shall request approval from HIV EPIDEMIOLOGY PROGRAM (HEP) in writing a minimum of thirty (30) days before terminating services at such location and before commencing services at any other locations.

- 4. <u>COUNTY'S MAXIMUM OBLIGATION</u>: During the period of January 1, 2004 through June 30, 2004, that portion of County's maximum obligation which is allocated under this Exhibit for the HIV/AIDS Adult Spectrum of HIV-Related Diseases Cohort Study shall not exceed One Hundred Sixty Thousand, Four Hundred Twenty Dollars (\$160,420).
- 5. <u>COMPENSATION</u>: County agrees to compensate Contractor for performing services hereunder for actual reimbursable net cost as set forth in Schedule 3-A. Payment for services provided hereunder shall be subject to the provisions set forth in the PAYMENT Paragraph of this Agreement.
- 6. SERVICES TO BE PROVIDED: Contractor shall conduct the HIV/AIDS Adult Spectrum of HIV-Related Diseases Cohort Study in accordance with procedures formulated and adopted by Contractor's staff, consistent with law, regulations, and the terms of this Agreement. Services to be provided shall include, but shall not be limited to:
  - A. Identifying and enrolling all patients with HIV disease or an AIDS diagnosis age thirteen (13) years and older.
  - B. Reviewing the medical records to abstract diagnostic treatment and laboratory information for each admission.
    - C. Maintaining data on all study participants.
    - D. Tracking enrolled participants throughout the study.

- 7. <u>REPORTS</u>: Subject to the reporting requirements of the REPORTS Paragraph of the ADDITIONAL PROVISIONS of this Agreement attached hereto, Contractor shall submit the following reports:
  - A. Monthly Report: Contractor shall submit to HEP a monthly report no later than thirty (30) days after the end of each calendar month. Monthly reports shall clearly reflect all required information as specified, in a narrative report format, identifying the progress of the study as provided by HEP.
  - B. Annual Report: Contractor shall submit to HEP an annual report within the time period as directed for each year. Annual reports shall include all the required information and be completed in the correct format.
- 7. ANNUAL TUBERCULOSIS SCREENING FOR STAFF: Prior to employment or provision of services hereunder, and annually thereafter, Contractor shall obtain and maintain documentation of tuberculosis screening for each employee, volunteer, and consultant providing services hereunder. Such tuberculosis screening shall consist of tuberculin skin test (Mantoux test) and/or written certification by a physician that the person is free from active tuberculosis based on a chest x-ray.

Contractor shall adhere to Exhibit C, "Guidelines for Staff Tuberculosis Screening", attached hereto and incorporated herein

by reference. Director shall notify Contractor of any revision of these Guidelines, which shall become part of this Agreement.

- 8. <a href="PROGRAM RECORDS">PROGRAM RECORDS</a>: Contractor shall, at a minimum, maintain program/participant records as follows:
  - A. Each participant's record shall include, but shall not be limited to, documentation of HIV disease, and/or AIDS diagnosis.
  - B. Documentation of supervisorial review of each participant's record.
- 9. QUALITY IMPROVEMENT: Contractor shall develop and submit to HEP within ninety (90) days of the execution of this Agreement, its written Quality Improvement (QI) program. The program shall include requirements for an internal QI committee, a mechanism for obtaining client input, and identify the QI program's structure, process, and desired outcome.

### HIV EPIDEMIOLOGY PROGRAM ADULT SPECTRUM OF HIV-RELATED DISEASE PROJECT (ASD) SUBCONTRACT: LAC+USC/HRA

### January 1, 2004 - June 30, 2004

		MONTHLY SALARY	% TIME	# of MOS	# of POS	TOTAL
1.	PERSONNEL	OALAITI	1 11417	WOS	FU3	TOTAL
	HRA Personnel (Full-time)					
	Research Analyst II	4,077	100%	6	1	24,462
	Research Analyst I	3,036	100%	6	1	18,216
	Research Analyst I	3,036	50%	6	1	9,108
	Subtotal HRA Salaries					51,786
	USC Personnel (Part-time)					
	Co-Principal Investigator (A. Kovacs, M.	14,325	5%	6	1	4,298
	Program Coordinator (W. Du)	4,721	10%	6	1	2,832
	Medical Records Abstractor (J. Ahmed)	3,167	25%	6	1	4,750
	Medical Records Abstractor (M. Rahmar	3,027	100%	6	1	18,162
	Data Coordinator (D. Goodner)	2,750	75%	6	1	12,375
	Subtotal USC Salaries					42,417
	Total Salaries					94,203
	Employee Benefits (HRA) @ 23%					11,911
	Employee Benefits (USC) @ 33.75%					14,316
	Total Employee Benefits					26,227
	Total Personnel					120,430
II.	OPERATING EXPENSES					
	Mileage/Travel					1,038
	Office Supplies					415
	Total operating Expenses					1,453
111.	INDIRECT COST (32% of Total Personnel)					20 527
••••						38,537
IV.	TOTAL SUB-CONTRACT					\$160,420

## HUMAN IMMUNODEFICIENCY VIRUS (HIV) ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS) ADULT SPECTRUM OF HIV-RELATED DISEASES COHORT STUDY SERVICES AGREEMENT

Amendment No. 2

	THIS AMENDMENT is	s made and	entered into this day
of _		, 2004,	
	by and between		COUNTY OF LOS ANGELES (hereafter "County"),
	and		KAISER FOUNDATION RESEARCH INSTITUTE on behalf of KAISER FOUNDATION HOSPITALS, INC. (hereafter "Kaiser Permanente" or "Contractor").

WHEREAS, reference is made to that certain document entitled "HUMAN IMMUNODEFICIENCY VIRUS (HIV) ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS) ADULT SPECTRUM OF HIV-RELATED DISEASES COHORT STUDY SERVICES AGREEMENT", dated October 15, 2002, and any amendments thereto, further identified as Agreement No. H-207839 (hereafter "Agreement"); and

WHEREAS, it is the intent of the parties hereto to reduce the term of the Agreement and to provide for other changes set forth herein; and

WHEREAS, said Agreement provides that changes may be made in the form of a written Amendment which is formally approved and

executed by the parties; and

NOW, THEREFORE, the parties agree as follows:

- 1. This Amendment shall be effective January 1, 2004.
- 2. Paragraph 2, <u>DESCRIPTION OF SERVICES</u>, shall be amended to read as follows:
  - "2. <u>DESCRIPTION OF SERVICES</u>: Contractor shall provide services as described in Exhibits A and C-1 attached hereto and incorporated herein by reference ."
- 3. Exhibit C shall be deleted in its entirety and shall be replaced by Exhibit C-1.
- 4. The first two subparagraphs of Paragraph 1, <u>TERM</u>, shall be amended to read as follows:
  - "1. TERM: The term o f this Agreement shall commence on October 15, 2002 and continue in full force and effect through December 31, 2003. Said Agreement shall thereafter be automatically renewed for one (1) six-month period, effective January 1, 2004 through June 30, 2004, subject to the availability of federal, State, or County funding sources. This Agreement may be terminated, with or without cause, by contractor upon giving at least thirty (30) days advance written advance written notice thereof to County. In any event County may terminate this Agreement in accordance with the ADDITIONAL PROVISIONS hereunder.

County may also suspend the performance of services hereunder, in whole or in part, within thirty (30) days notice to Contractor. County's notice shall set forth the reasons for the suspension, the extent of the suspension, and the requirements for full restoration of the performance obligations."

5. Paragraph 3, <u>MAXIMUM OBLIGATION OF COUNTY</u>, shall be amended to read as follows:

### "3. MAXIMUM OBLIGATION OF COUNTY:

- A. During the period January 1, 2002 through
  December 31, 2002, the maximum obligation of County for
  all services provided hereunder shall not exceed One
  Hundred Twelve Thousand, Four Hundred Forty-Four Dollars
  (\$112,444). Such maximum obligation is comprised
  entirely of Federal Centers for Disease Control and
  Prevention, HIV/AIDS Surveillance and Seroprevalence
  Program funds. This sum represents the total maximum
  obligation of County as shown in Schedule 1, attached
  hereto and incorporated herein by reference.
- B. During the period January 1, 2003 through
  December 31, 2003, the maximum obligation of County for
  all services provided hereunder shall not exceed One
  Hundred Twenty-Seven Thousand, Eight Hundred Sixteen

- (\$127,816). Such maximum obligation is comprised entirely of Federal Centers for Disease Control and Prevention, HIV/AIDS Surveillance and Seroprevalence Program funds. This sum represents the total maximum obligation of County as shown in Schedule 2, attached hereto and incorporated herein by reference.
- C. During the period January 1, 2004 through June 30, 2004, the maximum obligation of County for all services provided hereunder shall not exceed Sixty-Nine Thousand, One Hundred Twenty-Eight (\$69,128). Such maximum obligation is comprised entirely of Federal Centers for Disease Control and Prevention, HIV/AIDS Surveillance and Seroprevalence Program funds. This sum represents the total maximum obligation of County as shown in Schedule 3-A, attached hereto and incorporated herein by reference."
- 6. Paragraph 6, <u>COMPENSATION</u>, shall be amended to read as follows:
  - "6. <u>COMPENSATION</u>: County agrees to compensate

    Contractor for performing services hereunder for actual

    reimbursable net cost as set forth in Schedules 1, 2, and

    3-A, and the PAYMENT Paragraph of this Agreement."
- 7. Schedule 3 shall be deleted in its entirety and be replaced with Schedule 3-A.

- 8. Schedule 4 shall be deleted in its entirety from Agreement.
- 9. Paragraph 7, <u>CONFLICT OF TERMS</u>, Agreement shall be amended to read as follows:
  - "7. <u>CONFLICT OF TERMS</u>: To the extent there exists any conflict between the language of this Agreement and that of any of the exhibits and schedules attached hereto, the language in this Agreement shall govern and prevail, and the remaining exhibits and schedules shall govern and prevail in the following order:

Exhibits A and C-1
Schedules 1, 2, and 3-A
Exhibit B"

- 10. Exhibit C-1, SCOPE OF WORK FOR HIV/AIDS ADULT SPECTRUM OF HIV-RELATED DISEASES COHORT STUDY SERVICES is attached to this Amendment and is incorporated in Agreement by reference.
- 11. Schedule 3-A, BUDGET FOR HIV/AIDS ADULT SPECTRUM OF HIV-RELATED DISEASES COHORT STUDY SERVICES, is attached to this Amendment and incorporated in Agreement by reference.
- 12. Except for the changes set forth hereinabove, Agreement shall not be changed in any respect by this Amendment.

IN WITNESS WHEREOF, the Board of Supervisors of the County of Los Angeles has caused this Amendment to be subscribed by its

Director of Health Services, and Contractor has caused this Amendment to be subscribed in its behalf by its duly authorized officer, the day, month, and year first above written.

COUNTY OF LOS ANGELES
By Thomas L. Garthwaite, M.D. Director and Chief Medical Officer
KAISER FOUNDATION RESEARCH INSTITUTE on behalf of KAISER FOUNDATION HOSPITALS, INC.
Contractor
Ву
Signature
Printed Name
Title
(AFFIX CORPORATE SEAL)
Y COUNSEL

APPROVED AS TO FORM BY THE OFFICE OF THE COUNT LLOYD W. PELLMAN County Counsel

APPROVED AS TO CONTRACT ADMINISTRATION:

Ву \_\_ Contract Administration

cd3109es.wpd

### EXHIBIT C

### KAISER FOUNDATION RESEARCH INSTITUTE

### HUMAN IMMUNODEFICIENCY VIRUS (HIV) ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS) ADULT SPECTRUM OF HIV-RELATED DISEASES COHORT STUDY

- 1. <u>DEFINITION</u>: HIV/AIDS Adult Spectrum of HIV-Related Diseases Cohort Study is a medical records-based study to help better define the spectrum of HIV-related disease. Medical records are reviewed to collect basic demographic data, information on HIV-exposure category, AIDS-defining conditions, other infections and conditions, treatment and prophylaxis, and laboratory data.
- 2. <u>PERSONS TO BE SERVED</u>: HIV/AIDS Adult Spectrum of HIV-Related Diseases Cohort Study shall be conducted for all patients, thirteen (13) years and over, who have HIV disease or an AIDS diagnosis.
- 3. <u>SERVICE DELIVERY SITE</u>: Contractor's facility where services are to be provided hereunder is located at: Kaiser Permanente, 4867 Sunset Boulevard, Los Angeles, California 90027.

Contractor shall request approval from HIV EPIDEMIOLOGY PROGRAM (HEP) in writing a minimum of thirty (30) days before terminating services at such location and before commencing services at any other locations.

4. <u>COUNTY'S MAXIMUM OBLIGATION</u>: During the period of January 1, 2004 through June 30, 2004, that portion of County's

maximum obligation which is allocated under this Exhibit for the HIV/AIDS Adult Spectrum of HIV-Related Diseases Cohort Study shall not exceed Sixty-Nine Thousand, One Hundred Twenty-Eight Dollars (\$69,128).

- 5. <u>COMPENSATION</u>: County agrees to compensate Contractor for performing services hereunder for actual reimbursable net cost as set forth in Schedule 3-A. Payment for services provided hereunder shall be subject to the provisions set forth in the PAYMENT Paragraph of this Agreement.
- 6. <u>SERVICES TO BE PROVIDED</u>: Contractor shall conduct the HIV/AIDS Adult Spectrum of HIV-Related Diseases Cohort Study in accordance with procedures formulated and adopted by Contractor's staff, consistent with law, regulations, and the terms of this Agreement. Services to be provided shall include, but shall not be limited to:
  - A. Identifying and enrolling all patients with HIV disease or an AIDS diagnosis age thirteen (13) years and older.
  - B. Reviewing the medical records to abstract diagnostic treatment and laboratory information for each admission.
    - C. Maintaining data on all study participants.
    - D. Tracking enrolled participants throughout the study.

- 7. <u>REPORTS</u>: Subject to the reporting requirements of the REPORTS Paragraph of the ADDITIONAL PROVISIONS of this Agreement attached hereto, Contractor shall submit the following reports:
  - A. <u>Monthly Report</u>: Contractor shall submit to HEP a monthly report no later than thirty (30) days after the end of each calendar month. Monthly reports shall clearly reflect all required information as specified, in a narrative report format, identifying the progress of the study as provided by HEP.
  - B. Annual Report: Contractor shall submit to HEP an annual report within the time period as directed for each year. Annual reports shall include all the required information and be completed in the correct format.
- 8. ANNUAL TUBERCULOSIS SCREENING FOR STAFF: Prior to employment or provision of services hereunder, and annually thereafter, Contractor shall obtain and maintain documentation of tuberculosis screening for each employee, volunteer, and consultant providing services hereunder. Such tuberculosis screening shall consist of tuberculin skin test (Mantoux test) and/or written certification by a physician that the person is free from active tuberculosis based on a chest x-ray.

Contractor shall adhere to Exhibit B, "Guidelines for Staff Tuberculosis Screening", attached hereto and incorporated herein

by reference. Director shall notify Contractor of any revision of these Guidelines, which shall become part of this Agreement.

- 9. <u>PROGRAM RECORDS</u>: Contractor shall, at a minimum, maintain program/participant records as follows:
  - A. Each participant's record shall include, but shall not be limited to, documentation of HIV disease, and/or AIDS diagnosis.
  - B. Documentation of supervisorial review of each participant's record.
- 10. QUALITY IMPROVEMENT: Contractor shall develop and submit to HEP within ninety (90) days of the execution of this Agreement, its written Quality Improvement (QI) program. The program shall include requirements for an internal QI committee, a mechanism for obtaining client input, and identify the QI program's structure, process, and desired outcome.

# COUNTY OF LOS ANGELES - DEPARTMENT OF HEALTH SERVICES HIV EPIDEMIOLOGY PROGRAM ADULT SPECTRUM OF HIV - RELATED DISEASE COHORT STUDY SUBCONTRACT: KAISER-SUNSET

January 1, 2004 - June 30, 2004

		Monthly	# of	% of	# of	
١.	PERSONNEL	Personnel	Pos.	Time	Mos.	Total
	Co-Principal Investigator	13,930	1	2.5%	6	2,090
	Research Assistant	3,322	1	60%	6	11,958
	Site Coordinator	3,314	1	85%	6	16,903
	Total Salaries					30,951
	Employee Benefits @ 42% of total salar	ies				13,000
	Total Personnel					43,951
II.	OPERATING EXPENSES					
	Office Supplies					1,000
	Mileage/Travel					2,000
	Medical Records Retrieval					2,400
	Total Operating Expenses					5,400
Ш	. INDIRECT COSTS @ 45% (total perso	nnel)				19,777
IV	. TOTAL SUB-CONTRACT				\$69,128	

S:/Grants/CDCPro04/SurvSero/ASDCONTO